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Information Disclosure Statement

3. The listing or citing of references in applicant's response is not a proper information disclosure statement.

Applicant's Response Dated April 12, 2006

4. Claims 25-34 are pending. Claims 28-34 are withdrawn from further consideration as being drawn on nonelected invention. An action on the merit of claims 25-27 is considered herein below.

5. The rejection of claims 25-27 under 35 U. S. C. 102(b) as being anticipated by Sanchez Palacios A. et. Al. is maintained for the reasons of record as set forth in the Office Action dated November 21, 2005.

Rejection of Record Set Forth in the Office Action Dated November 21,2005

6. The text of those actions .....

7. Claims 25-27 are rejected under 35 U. S. C. 102(b) as being anticipated by Sanchez Palacios A. et. al. Allergol Immunopathos (Madr) (1992), Vol 20 (1), pages 35-39 (Sanchez).

Sanchez discloses the use of Immunoferom (AM3) in the treatment of childhood infectious respiratory pathology. To assess the immunoclinical effectiveness of a biologic response immunomodulator, glycophosphopeptide (AM3) was administered to 20 children with asthmatic bronchitis. ..... ect

8. Aplicant's argument filed April 12, 2006 have been fully considered but they are not persuasive.....

Applicant's arguments have been considered but are not deemed germane. Sanchez teaches the use of glycophosphopeptide for treating asthmatic bronchitis. It was well known in the art at the time of the invention that asthmatic bronchitis is a condition in which the airways in the lung are obstructed due to both persistent asthma and bronchitis. Thus, the patient population treated by the method of Sanchez embraces asthma patients and therefore meets the limitation of the instantly claimed invention.

Reply to points 4 – 7 inclusive and point 8 that are raised by the Examiner.

The Examiner Search Strategy and Results 06-2802006

The confusion arises because we are dealing with diseases clinically presented with cough wheeze and dyspnoea

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I am still arguing that asthma and asthmatic bronchitis are separate unrelated diseases "confusion in the name" by the old terminology of "asthmatic bronchitis" [They also use a term of "cardiac asthma" to denote dyspnoea with heart failure (Annex II)]), and that the use of glycophosphopeptical in asthma is novel. Therefore, I am submitting new clear medical evidence that clarifies the correlation between asthma and asthmatic bronchitis; according to Caroline Breese Hall and John T. McBride selected from Annex I: "We are dealing with two separate diseases that may coexist in an infant, and that children with bronchiolitis in infancy have no increased risk of asthma by the time they reach adolescence." This will be detailed further in the following text. May I kindly ask the Examiner to consider this new evidence.

Selected chapters are photocopied, and the relevant paragraphs are underlined in order to clarify the source of confusion in the name, the differentiating clinical features, and the correlation between asthmatic bronchitis and asthma. I am trying to keep the text minimal, but excuse me for placing some paragraphs and sentences of secondary importance to keep the continuity of the reply. May I kindly ask the Examiner to consider this new evidence

New clear scientific and medical evidence are being submitted that clarifies the correlation between asthma and asthmatic bronchitis "We are dealing with two separate diseases that may coexist in an infant, and that children with bronchiolitis in infancy have no increased risk of asthma by the time they reach adolescence." This will be detailed further, and are selected from Annex I- Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

Selected from the textbook of Principles and Practice of Infectious Diseases 2005 (Annex 1), Dr. Caroline Breese Hall and John T. McBride in the chapter titled "Bronchiolitis", are clarifying "the source of confusion in the name;" "We are dealing with two separate diseases that may coexist in an infant up to 2 years of age, and that children with bronchiolitis in infancy have no increased risk of asthma by the time they reach adolescence." (page(page XXX coloum XX paragraph XX).

"Bronchiolitis is an acute viral lower respiratory tract illness that occurs during the first 2 years of life. The illness also has been called "wheezy bronchitis" and "asthmatic bronchitis". Whatever term is applied, the syndrome is caused primarily by viral infections. The characteristic clinical manifestations include an acute onset of wheezing and hyperinflation, most commonly associated with cough, rhinorrhea, tachypnoea (increased respiratory rate) and respiratory distress." (page XXX coloum XX paragraph XX).

"The term bronchiolitis appears to have been born from a long lineage of confusing sobriquets, including "acute catarrhal bronchitis," "interstitial bronchopneumonia," "spastic bronchopneumonia," "capillary or obstructive bronchiolitis," and "asthmatic

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bronchitis." Bronchiolitis, however, did not become recognized as a distinct entity until the 1940s." (page XXX coloum XX paragraph XX).

Terminology or Definitions

The term asthma, historically, is used to designate any disease characterized by "asthma-like symptoms", that are unrelated to the disease entity of current asthma. It has been used to describe patients complaining of shortness of breath (dyspnoea), wheeze (audible respiration), cough and sputum. As an example of this is the term cardiac asthma (a clinical manifestation of heart failure) and asthmatic bronchitis (a viral respiratory disease affecting infants and young children below 2 years of age)

1- Cardiac Asthma

Is a clinical manifestation of heart failure. Cardiac asthma is closely related to paroxysmal nocturnal dyspnoea and nocturnal cough and is characterized by wheezing secondary to bronchospasm-most prominent at night.

- Part VIII Disorders of the Cardiovascular System. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE. 16th Edition (2005): page 1370. Mc Graw-Hill

2- Asthmatic Bronchitis

Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

Annexes:

Annex 1. Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

Claims

Detailed Reply

Summary

The search conducted by The Examiner according to PAIR is related to the disease groups manifested clinically by the triad of cough dyspnoea and wheeze and possible

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diseases that can cause this triad are acute reparatory viral infection in the first 2 years of life in asthmatic bronchitis (bronchiolitis), or allergic relapsing as in asthma and as a result of smoking in chronic obstructive pulmonary disease (COPD).

The correlation between asthma and asthmatic bronchitis according to Annex I, and as detailed below

In page 812, column 2, the following statement is written:

"Bronchiolitis is an acute viral lower respiratory tract illness that occurs during the first 2 years of life. The illness has been called "Wheezy bronchitis" and "asthmatic bronchitis."

In page 816, column 1, under the subtitle Diagnosis, the following statement is written:

"The diagnosis of bronchiolitis is made most frequently on the basis of the characteristic clinical and epidemiologic findings. However, considerable confusion exists over the exact definition of bronchiolitis. A variety of entities may cause similar picture of dyspnoea and wheezing in the infant. Asthma is not easily differentiated, particularly if it is the infant's first episode. Furthermore, the two diseases may be combined.

In page 815, column 1, last paragraph, the following statement is written:

"Nevertheless, the association between bronchiolitis and asthma is not straightforward. Several investigators have demonstrated that children with bronchiolitis in infancy have no increased risk of asthma or abnormal pulmonary function by the time they reach early adolescence."

	Asthmatic bronchitis (Bronchiolitis)	Bronchial asthma
Age limitation		
Causative agent	Respiratory syncytial virus	Type I hypersensitivity reaction
Pathophysiology	Tissue necrosis,	Bronchoconstriction, mucosal edema, excessive secretion
Clinical presentation	Wheeze, dyspnoea, cough and sputum	Wheeze, dyspnoea, cough and sputum
Treatment	Antiviral agents	Bronchodilators, inhaled corticosteroids as controller medications, anti-leukotriens and others

Annex I- Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

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Asthmatic Bronchitis (Bronchiolitis)
Annex I

Detailed description of this disease was available from a textbook of "Principles and Practice of Infectious Diseases".

Bronchiolitis is an acute viral lower respiratory tract illness that occurs during the first 2 years of life. The illness also has been called "wheezy bronchitis" and "asthmatic bronchitis". Whatever term is applied, the syndrome is caused primarily by viral infections. The characteristic clinical manifestations include an acute onset of wheezing and hyperinflation, most commonly associated with cough, rhinorrhea, tachypnoea (increased respiratory rate) and respiratory distress.

The term bronchiolitis appears to have been born from a long lineage of confusing sobriquets, including "acute catarrhal bronchitis," "interstitial bronchopneumonia," "spastic bronchopneumonia," "capillary or obstructive bronchiolitis," and "asthmatic bronchitis." Bronchiolitis, however, did not become recognized as a distinct entity until the 1940s.

Etiology (P 812):

Respiratory syncytial virus (RSV) is clearly the major pathogen, and the parainfluenza virus is the second most commonly isolated agent.